



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,540	02/08/2002	James Arthur Hoffmann	X-11368A	4243

25885 7590 09/26/2006

ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER

ZHANG, NANCY L

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,540	Applicant(s) HOFFMANN, JAMES ARTHUR	
	Examiner Nancy L. Zhang	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41 and 44-54 is/are rejected.
- 7) ☒ Claim(s) 42 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed December 27, 2004 has been received. Applicant's remarks that the rejection in the last office action is an improper rejection have been considered and are found persuasive. The previous Double-Patenting rejection is therefore withdrawn.

Claims 35-54 are presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4 of U.S. Patent No. 6,358,924 (Hoffmann; issue date: Mar. 19, 2002). Although the conflicting claims are not identical,

Art Unit: 1614

they are not patentably distinct from each other. The only difference between them is: the surfactant in claims 35-38 of the instant application is a Tween polymeric surfactant whereas the surfactant in claims 1 and 4 of Hoffmann's issued patent is a list of anionic surfactant. Although a Tween polymeric surfactant is not in the list of anionic surfactant in the claims of the issued patent, a Tween polymeric surfactant can be an anionic surfactant (DeFazio, US Patent 4,447,545, issued date: May 08, 1984, column 5, lines 38-39). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an anionic Tween polymeric surfactant as the anionic surfactant in the formulation of Hoffmann's issued patent.

Claim 36 recites that the GLP-1 compound is protected from the activity of dipeptidyl-peptidase IV. This is merely a recitation of mechanism of the stable pharmaceutical formulation.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the

Art Unit: 1614

applicants to “prove that subject matter shown to be in the prior art does not possess characteristic relied on” (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35, 39-41 and 44-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudsen (US Patent 6,458,924; issue date: Oct. 1, 2002; filing date: Sep. 16, 1999).

Claims 35, 39-41 and 44-52 recite a pharmaceutical formulation comprising a GLP-1 compound (selected from a group consisting of GLP-1, GLP-1 analogs and GLP-1 derivatives), a Tween polymeric surfactant, a preservative and a buffer (pH about 6.5

Art Unit: 1614

to about 9.0). Claims 48-50 recite that the formulation further comprises an isotonicity agent.

Knudsen teaches a pharmaceutical composition comprising a GLP-1 derivative and a surfactant (see abstract). Knudsen also discloses that the pharmaceutical compositions preferably comprise a surfactant such as polymeric surfactants (Tween-40, Tween-80, Brij-35) (column 154, lines 36-37). The pH value for the buffers of Knudsen's composition can be 7.4 (column 201, table of examples). Knudsen's composition further comprises an isotonic agent, a preservative and a buffer (column 250, line 35).

Claim 39-41 and 44-46 of the instant application limit that the GLP-1 compound is acylated on the epsilon-amino acid group of lysine. Knudsen discloses that the GLP-1 derivative in the composition has its epsilon-amino acid group of Lys substituted with a lipophilic substituent which is an acyl group (column 249, lines 44-49).

Claims 45-46 of the instant application limit that the GLP-1 has an arginine at position 34. The GLP-1 derivative in Knudsen's composition has an arginine at position 34 (column 249, line 40).

Claim 49 of the instant application limits that the isotonicity agent is glycerin. Claim 50 of the instant application limits that the isotonicity agent is sodium chloride. Knudsen discloses that the isotonic agent in the composition is sodium chloride or glycerol (column 250, line 37).

Claim 51 of the instant application limits that the preservative is phenol. Claim 52 of the instant application limits that the preservative is m-cresol. Knudson discloses that the preservative is phenol or m-cresol (column 250, line 39).

Therefore, the pharmaceutical formulation of the instant application as claimed in claims 35, 39-41, 44-52 is clearly anticipated by Knudsen.

Claims 53-54 recite a method comprising administering a pharmacologically effective amount of a formulation of claim 35 for treating a person having a condition of elevated glucose levels. Claim 54 limits that the condition is Type II diabetes.

Knudsen teaches that the pharmaceutical composition of the invention may be administered parenterally to patients in need of a treatment (column 157, lines 13-15). Such treatment includes treating insulin dependent or non-insulin dependent diabetes mellitus (column 156, lines 62-64) which is Type II diabetes.

Therefore, the method of administering a formulation as claimed in claims 53-54 of the instant application is clearly anticipated by Knudsen.

In summary, Knudsen anticipates claims 35, 39-41 and 44-54.

Conclusion

Claims 42 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

nly 9/7/06

NLZ

Ardin H. Marschel 9/16/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER